UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Manley Stowell and Enid Stowell,

Plaintiffs,

v.

Civil No. 09-192 (JNE/FLN)
ORDER

Paul Huddleston, M.D. and Mayo Clinic-Rochester, a non-profit corporation,

Defendants.

David B. Ketroser, Esq., appeared for Plaintiffs Manley Stowell and Enid Stowell.

William R. Stoeri, Esq., and Meghan E. Lind, Esq., Dorsey & Whitney LLP, and Matthew J. Hanzel, Esq., Mayo Clinic Legal Department, appeared for Defendants Paul Huddleston, M.D., and Mayo Clinic-Rochester.

Manley and Enid Stowell (collectively, Plaintiffs) assert a claim of negligent nondisclosure against Dr. Paul Huddleston and the Mayo Clinic-Rochester (collectively, Defendants). The case is before the Court on Defendants' motion for summary judgment. For the reasons set forth below, the Court grants the motion.

I. BACKGROUND

A. Mr. Stowell's surgeries

Manley Stowell, a 67-year-old man, has a history of back problems. Several years ago, he underwent back surgery in Michigan. Two or three years later, Mr. Stowell underwent a second back surgery in Michigan. Hardware was implanted in his back during one of those surgeries. Neither surgery was successful. One of the screws implanted in Mr. Stowell's back eventually broke or came loose.

On March 2, 2006, Mr. Stowell underwent elective spine surgery at the Mayo Clinic-Rochester (Mayo) in an attempt to treat his back pain by fusing his spine between the L2 and S1 vertebrae. Dr. Huddleston, an orthopedic surgeon at Mayo, performed the surgery.[1] Dr. Huddleston believed Mr. Stowell's pain was caused at least in part by the broken screw and pseudoarthrosis.[2] Before the surgery, he warned Mr. Stowell about the risks of paralysis, stroke, and death. Dr. Huddleston warned Mr. Stowell that a stroke could cause changes in vision. Mr. Stowell testified that he was willing to undergo those risks because he wanted to eliminate his back pain. Mr. Stowell orally consented to the surgery, but Dr. Huddleston did not obtain an executed consent form.

The surgery took eleven hours, during which Mr. Stowell was in a prone position and lost approximately 3500 cubic centimeters of blood. Dr. Huddleston removed the hardware from Mr. Stowell's back, including the broken screw. When Mr. Stowell regained consciousness after the surgery, he was blind in both eyes. Dr. Jacqueline A. Leavitt, an ophthalmologist at Mayo, diagnosed the cause of Mr. Stowell's blindness as posterior ischemic optic neuropathy (PION) in both eyes.[3] Her clinical notes from that examination state:

> Discussed that [PION] is an unfortunate event that is seen rarely following surgery. I explained that this situation occurs from a stroke to both optic nerves and . . . that anesthesiologists, orthopedists, surgeons, and ophthalmologists around the country are very aware of this situation and have been trying to determine risk factors to no avail.

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[1] Orthopedics is the "specialty concerned with the preservation, restoration, and development of form and function of the musculoskeletal system, extremities, spine, and associated structures by medical, surgical, and physical methods." *Stedman's Medical Dictionary* 1277 (27th ed. 2000).

[2] Pseudoarthrosis is a "new, false joint arising at the side of an ununited fracture." *Id.* at 1469.

[3] An ophthalmologist specializes in the eye, its diseases, and refractive errors. *Id.* at 1268.

The March 2006 surgery did not eliminate Mr. Stowell's pain. Subsequent facet and sacroiliac joint testing and treatment reduced, but did not eliminate, his pain.

Plaintiffs filed suit in January 2009. They assert that Dr. Huddleston was negligent in failing to disclose the risk of blindness and the non-surgical alternative treatments of facet and sacroiliac joint testing and treatment.

B. Dr. Robin's affidavit

Plaintiffs retained Dr. Steven B. Robin, an ophthalmologist, as the expert required under Minn. Stat. § 145.682 (2008). On July 27, 2009, Plaintiffs served on Defendants the affidavit required by Minn. Stat. § 145.682, subds. 2(2), 4. On April 27, 2010, Plaintiffs filed an amended affidavit in response to Defendants' motion for summary judgment.[4]

Dr. Robin states in the amended affidavit that he agrees with Dr. Leavitt that, as of March 2, 2006, "'anesthesiologists, orthopedists, surgeons, and ophthalmologists around the country were very aware' that [PION] 'is an unfortunate event that is seen rarely following surgery.'" Dr. Robin opines that prolonged prone lumbar spine surgery is associated with a risk of permanent blindness, that the risk was discussed in the authoritative peer-reviewed literature before March 2, 2006, and that the risk was found to occur at a rate between 0.028% and 0.2% in all spine surgeries, depending on risk factors. Dr. Robin further opined that it was "accepted medical practice to know of the risk of permanent blindness from prolonged prone spine surgery." In addition, Dr. Robin describes his practice as including the performance of elective surgeries, some of which carry a known risk of blindness statistically similar to the risk of blindness associated with prolonged prone spine surgery. He opines that the standard of care in

[4] Defendants argue that the Court should not consider the amended affidavit because it is untimely. The Court does not address this issue because summary judgment is warranted even if the amended affidavit is considered.

Minnesota on March 2, 2006, required a reasonable physician—no specialty specified—to inform a patient of the risk of blindness from elective surgery when that risk was in the range of 0.028% to 0.2%.

Dr. Robin based his range of 0.028% to 0.2% on two journal articles attached to his amended affidavit. The first, dated June 1997, states that "[t]he risk of ophthalmic complications with spinal surgery has not been fully appreciated" and recommended a "cursory screening" of visual function in the immediate post-operative assessment of patients to permit immediate treatment of any visual abnormalities. The study discussed in the June 1997 article reviewed 3450 spine surgeries and stated that "ophthalmic complications" resulted in seven (0.2%) of the surgeries. Three of those complications were related to PION (0.09%) and one was related to anterior ischemic optic neuropathy (AION) (0.03%). One of the patients suffering PION reported blurry vision after surgery, but eventually recovered full vision. The other two patients who suffered PION reported decreased vision in one eye that had not completely returned as of their last follow-up appointment. None of the patients suffering from PION or AION were permanently blind.

The second article, dated June 21, 2005, summarized a twenty-year review of 14,102 spine surgeries and found that perioperative ischemic optic neuropathy (ION) had occurred in four (0.028%) of the cases. None of those four cases affected both eyes. In one case, the patient regained significant visual function in the affected eye. The abstract of the June 2005 article states that "[a]ll patients undergoing spine surgery should be informed about the low but definite risk of this condition." The body of the article, however, recommends only that "consideration be given to discussing this rare but potentially devastating complication with all patients for whom long duration back surgery, particularly that in the prone position, is contemplated." It

also noted that one earlier study had found the rate of perioperative ION neuropathy after spine surgery to be 0.0% and another earlier study had found the rate to be 0.12%.[5]

II. DISCUSSION

Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). The movant "bears the initial responsibility of informing the district court of the basis for its motion," and it must identify "those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the movant satisfies its burden, the party opposing the motion must respond by submitting evidentiary materials that "set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2); *see Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In determining whether summary judgment is appropriate, a court must look at the record and any inferences to be drawn from it in the light most favorable to the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

To succeed on a claim for negligent nondisclosure, a plaintiff must demonstrate: (1) a duty on the part of the physician to know of a risk or alternative treatment plan; (2) a duty to disclose the risk or alternative program, which may be established by showing that a reasonable person in what the physician knows or should have know to be the plaintiff's position would likely attach significance to that risk or alternative in deciding whether to consent to treatment;

[5] The 0.0% and 0.12% figures included incidents of PION and AION. The 0.12% figure was derived from the June 1997 article. The 0.0% figure was derived from a 2001 study that counsel for Plaintiffs represented was a Mayo Clinic study.

(3) breach of that duty; (4) causation (the undisclosed risk must materialize in harm); and (5) damages. *Plutshack v. Univ. of Minn. Hosps.*, 316 N.W.2d 1, 9 (Minn. 1982).

A plaintiff in a medical malpractice case must serve on the defendant with the summons and complaint an affidavit made by the plaintiff's attorney stating that an expert "whose qualifications provide a reasonable expectation that the expert's opinions could be admissible at trial" has reviewed the facts of the case and that, in the expert's opinion, the defendant deviated from the applicable standard of care, thereby causing injury to the plaintiff. Minn. Stat. § 145.682, subds. 2(1), 3(a). The plaintiff must also serve on the defendant within 180 days after the commencement of the suit an affidavit that identifies the expert or experts who will testify at trial and summarizes "the substance of the facts and opinions to which the expert is expected to testify, and a summary of the grounds for each opinion." *Id.* § 145.682, subds. 2(2), 4(b). Failure to comply with the expert witness disclosure requirements requires, on motion, mandatory dismissal with prejudice of each cause of action as to which expert testimony is necessary to establish a prima facie case. *Id.* § 145.682, subd. 6(b).

A witness who is not qualified to give an expert opinion does not meet the expert witness disclosure requirements set forth in the statute. *Broehm v. Mayo Clinic Rochester*, 690 N.W.2d 721, 726 (Minn. 2005). Whether an expert is qualified to provide expert medical testimony depends on the degree of the witness's scientific knowledge and the extent of the witness's "practical experience with the matter which is the subject of the offered testimony." *Reinhardt v. Colton*, 337 N.W.2d 88, 93 (Minn. 1983). As explained by the Minnesota Supreme Court in *Cornfeldt v. Tongen*,

> [The medical expert] must have had basic education and professional training as a general foundation for his testimony, but it is a practical knowledge of what is usually and customarily done by physicians under circumstances similar to those which confronted the defendant charged with malpractice that is of controlling

> importance in determining competency of the expert to testify to the degree of care against which the treatment given is to be measured.

262 N.W.2d 684, 692-93 (Minn. 1977) (quotation marks omitted).

A. Nondisclosure of risk of PION

Defendants contend that dismissal is warranted because Plaintiffs have not met the expert affidavit requirement for the "duty to disclose" element of their negligent nondisclosure claim. Under Minnesota law, a plaintiff may establish a duty to disclose by showing that a skilled practitioner of good standing would have revealed the risk. *K.A.C. v. Benson*, 527 N.W.2d 553, 561 (Minn. 1995). A plaintiff may also establish a duty to disclose by showing that there was a risk of death or serious bodily harm which was a significant probability.[6] *Id.*

1. Skilled practitioner

In a negligent nondisclosure case, qualified expert testimony is required to establish the risks similarly skilled practitioners would disclose under similar circumstances. *Kohoutek v. Hatner*, 383 N.W.2d 295, 299 (Minn. 1986); *Adolphson v. United States*, 545 F. Supp. 2d 925, 930 (D. Minn. 2008). Plaintiffs maintain that Dr. Robin is qualified to testify as an expert about which risks a skilled practitioner would disclose because he has a "similar practice" to Dr. Huddleston in that Dr. Robin treats "private patients in all age groups."

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[6] Relying on the discussion in *Cornfeldt* of a case decided by the California Supreme Court, Plaintiffs suggest that the duty to disclose encompasses all risks of serious bodily harm regardless of their probability. Plaintiffs cite no Minnesota case adopting this standard, and subsequent cases from the Minnesota Supreme Court indicate that the duty to disclose risks of serious bodily harm extends only to those that are a "significant probability." *See, e.g.*, *K.A.C.*, 527 N.W.2d at 561 ("Doctors have a duty to disclose risks of death or serious bodily harm which are a significant probability."); *Kinikin v. Heupel*, 305 N.W.2d 589, 595 (Minn. 1981) ("A physician must disclose risks of death or serious bodily harm which are of significant probability; to this there is no contention."). Similarly, Plaintiffs' contention that Dr. Huddleston should have disclosed the risk of PION because he was aware of an "association" between it and prolonged prone spine surgery is unpersuasive because knowledge of the association does not establish that the risk was significant. Plaintiffs cite no authority requiring a doctor to disclose every risk of which he is aware, no matter how remote.

Here, the circumstances surrounding the alleged malpractice are the performance of prolonged prone spine surgery on a man in his early sixties. Nothing in Dr. Robin's affidavit indicates that he has any experience performing surgeries similar to a prolonged prone spine surgery on patients similar to Mr. Stowell under similar circumstances. Dr. Robin is an eye surgeon, not a spine surgeon. His ophthalmological practice, even if it extends to treating private patients of all ages, is insufficient to establish his knowledge of or experience with what warnings are customarily given by orthopedic surgeons prior to performing prolonged prone spine surgery on a patient similar to Mr. Stowell. *See, e.g. Teffeteller v. Univ. of Minn.*, 645 N.W.2d 420, 426-27 (Minn. 2002) (affirming exclusion of expert in general pediatrics with no specialization in pediatric oncology and no experience with bone marrow transplants as unqualified to testify regarding the customary response for physicians treating bone marrow transplant patients); *Wall v. Fairview Hosp. and Healthcare Servs.*, 584 N.W.2d 395, 405 (Minn. 1998) (finding psychologist and psychotherapist not qualified to provide expert opinion about the appropriate standard of care for a psychiatric nurse because they lacked the requisite scientific background and practical experience of supervising a psychiatric nurse); *Cornfeldt*, 262 N.W.2d at 694 (affirming exclusion of testimony from pathologist about standard of care of anesthesiologist, surgeon, and surgical resident where pathologist had little training in anesthesiology). Consequently, Dr. Robin is not qualified to testify about what warnings a skilled orthopedic surgeon would have given under similar circumstances to a patient such as Mr. Stowell in March 2006.

2. Significant risk of serious bodily harm or death

In negligent nondisclosure cases, expert testimony is required to establish that a risk of serious bodily harm or death exists and that it is accepted medical practice to know of that risk.

Reinhardt, 337 N.W.2d at 96. A plaintiff must also produce expert testimony establishing the gravity of the risk and the likelihood of its occurrence. *Cornfeldt*, 262 N.W.2d at 702. Nothing in Dr. Robin's affidavit indicates that he has any training or experience relevant to the likelihood that PION would result from a prolonged prone spine surgery or whether orthopedic surgeons knew of that risk and its likelihood. Consequently, Dr. Robin is not qualified to testify on either topic. *See Williams v. Wadsworth*, 503 N.W.2d 120, 125 (Minn. 1993) (affirming exclusion of expert testimony of cardiologist whose lack of familiarity with the use of a lymphangiogram as a diagnostic tool indicated that he lacked the necessary expertise to offer an opinion as to the risks associated with its performance and the information a radiologist should have provided in obtaining consent); *Reinhardt*, 337 N.W.2d at 93-94 (affirming exclusion of pathologist who had never prescribed a particular drug to treat rheumatoid arthritis, never treated a patient using the drug, and never made a diagnosis of rheumatoid arthritis as not qualified to testify regarding risks associated with using the drug to treat rheumatoid arthritis).

Dr. Robin's ability to locate the June 1997 and June 2005 journal articles does not cure his lack of qualification.[7] As an initial matter, Dr. Robin misstates the conclusions of the journal articles. First, he states the "risk of permanent blindness" was found to be 0.2% in the June 1997 article. None of the patients discussed in the June 1997 article were permanently blind or suffered a complete loss of vision, however, and the risk of PION-induced loss of vision was 0.09%, not 0.2%. Similarly, Dr. Robin states the risk of permanent blindness found in the June 2005 article was 0.028%. Of the four cases of perioperative ION discussed in the June 2005 article, only three were permanent, reducing the incidence of permanent blindness to 0.021%.

[7] Dr. Robin's reliance on those journal articles is questionable because Plaintiffs offered no evidence indicating they are the type of facts or data reasonably relied upon by experts in the field. *See* Fed. R. Evid. 703.

Moreover, all four cases were "characterized by loss of vision in one eye," not by blindness in both eyes. In short, the statistics cited by Dr. Robin do not represent the risk of the harm—PION-induced permanent blindness in both eyes—actually suffered by Mr. Stowell. Moreover, Dr. Robin did not explain why the statistics and recommendations in the journal articles differed or how they might predict the probability of the harm suffered by Mr. Stowell, nor is there any indication that he is qualified to do so.[8]

Finally, Plaintiffs maintain that the June 1997 and June 2005 journal articles, standing alone, establish the significance of the risk of PION-induced permanent blindness after prolonged prone spine surgery. This argument is unpersuasive for several reasons. First, for the reasons stated above, the journal articles do not establish the likelihood of the risk of PION-induced permanent blindness. Second, the journal articles recommend only a post-operative screening or that doctors *consider* giving a warning about PION, not a duty to disclose the risk in March 2006. Third, as previously stated, expert testimony, not journal articles authored by non-testifying experts, is required to establish a duty to disclose and the likelihood of the risk.[9] *See Cornfeldt*, 262 N.W.2d at 702. Finally, the journal articles are inadmissible hearsay because they are out-of-court statements offered to show the likelihood that PION would occur or to establish a duty to disclose the risk of PION-induced permanent blindness. *See* Fed. R. Evid. 801.

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[8] Counsel for Plaintiffs attempted to explain the differences at oral argument, but Plaintiffs cannot use attorney argument to fill in gaps in the statutorily-required expert affidavits. *Cf. Stroud v. Hennepin County Med. Ctr.*, 556 N.W.2d 552, 555 (Minn. 1996) ("The Minnesota legislature enacted Minn. Stat. § 145.682 for the purpose of eliminating nuisance medical malpractice lawsuits by requiring plaintiffs to file affidavits verifying that their allegations of malpractice are well-founded.").

[9] Plaintiffs argue that Dr. Robin is qualified to testify about the duty to disclose because he performs surgeries having a risk of blindness between 0.028% and 0.2%. This argument is unpersuasive because, for the reasons stated above, no qualified expert testimony (or other evidence) establishes that the risk of permanent PION-induced blindness following prolonged prone spine surgery falls within that range.

3. Practice advisory and Dr. Leavitt's clinical notes

Plaintiffs maintain that a June 2006 "practice advisory" and Dr. Leavitt's clinical notes establish a duty to disclose the risk of PION. Even if the practice advisory and clinical notes could substitute for the expert affidavit required by Minn. Stat. § 145.682, neither establishes a duty to disclose.

First, no evidence indicates that Dr. Leavitt, an ophthalmologist, is qualified to opine about what warnings orthopedic surgeons customarily give before surgeries such as that performed on Mr. Stowell. Moreover, her statement that doctors are "very aware" of the risk of PION following surgery does not establish the likelihood that PION would occur, that the risk is significant enough to require a warning, or that such a warning is customary.

As for the June 2006 practice advisory, it is inadmissible hearsay when offered to establish a duty to disclose. *See* Fed. R. Evid. 801(c). Although Plaintiffs contend the practice advisory is nonhearsay under Rule 801(d)(2) of the Federal Rules of Evidence because one of its authors is a Mayo anesthesiologist, they have not met their burden of establishing that the practice advisory falls within the scope of Rule 801(d)(2). *See Am. Eagle Ins. Co. v. Thompson*, 85 F.3d 327, 333 (8th Cir. 1996) (holding that party seeking admission of evidence under Rule 801(d)(2)(D) was required to establish a foundation demonstrating that the out-of-court declarant met the requirements of the rule). Moreover, the practice advisory merely states that doctors should "[c]onsider informing patients in whom prolonged procedures, substantial blood loss, or both are anticipated" of a "small, unpredictable risk of perioperative visual loss" and determine on a case-by-case basis whether they should warn non-high-risk patients. A recommendation that doctors "consider" warning of the risk of PION is insufficient to establish a duty to disclose. Further, the practice advisory states that such advisories are "not intended as standards,

guidelines, or absolute requirements." Finally, the practice advisory, which was published two months after Mr. Stowell's operation, cannot be used to establish the standard of care before its publication.[10] *See Adolphson*, 545 F. Supp. 2d. at 932 (explaining that relying on the same practice advisory to establish standard of care before June 2006 "would be tantamount to finding Galen, Hippocrates, or Lister negligent for failing to prescribe or use penicillin"). For the reasons stated above, the Court grants summary judgment on Plaintiffs' claim insofar as it is based on the failure to disclose the risk of PION-induced permanent blindness.[11]

B. Failure to obtain signed consent form and nondisclosure of alternatives to surgery

Plaintiffs allege that Dr. Huddleston's failure to obtain an executed consent form from Mr. Stowell before the surgery caused Mr. Stowell's blindness. Plaintiffs, however, offer no evidence indicating that a signed consent form would have informed Mr. Stowell of the risk of blindness or otherwise caused him to decline the surgery. Consequently, the Court grants summary judgment on Plaintiffs' claim insofar as it is based on the failure to obtain an executed consent form.

Plaintiffs also assert that Dr. Huddleston should have informed Mr. Stowell of the alternatives of facet and sacroiliac joint testing and treatment before the March 2, 2006 surgery. Drs. Huddleston and Chapman both testified that such treatment would not effectively resolve Mr. Stowell's pain, and Dr. Huddleston testified that he would never refer a patient with a broken screw or pseudoarthrosis for such treatment. Plaintiffs offer no evidence, expert or

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[10] At oral argument, Plaintiffs argued that Mayo knew of the practice advisory before Stowell's surgery because it was submitted for publication before March 2, 2006. Plaintiffs cite no support for the argument that the knowledge of one anesthesiologist at Mayo can be imputed to Mayo for purposes of establishing a pre-publication standard of care or duty to disclose.

[11] Defendants also maintain that Dr. Robin is not qualified to testify on the issue of causation. Having concluded that Plaintiffs have not met their burden with respect to a duty to disclose, the Court does not reach this issue.

otherwise, to the contrary. The Court therefore grants summary judgment on Plaintiffs' claim that Dr. Huddleston failed to disclose alternative treatments.[12]

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Defendants' Motion for Summary Judgment [Docket No. 12] is GRANTED.

2. This action is DISMISSED WITH PREJUDICE.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: July 9, 2010

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge

[12] Plaintiffs assert in their memorandum in response to Defendants' motion that Dr. Huddleston misrepresented the probability that the March 2006 surgery would completely eliminate Mr. Stowell's back pain. Plaintiffs did not allege any misrepresentation of the probability of success in their Complaint, nor have Plaintiffs moved for leave to amend their Complaint. Discovery closed on February 1, 2010. The Court will not consider a claim raised for the first time in response to a motion for summary judgment. *See N. States Power Co. v. Fed. Transit Admin.*, 358 F.3d 1050, 1057 (8th Cir. 2004) (explaining that parties are not "entitle[d] . . . to manufacture claims, which were not pled, late into the litigation for the purpose of avoiding summary judgment").